

## §476.108

does not identify an individual patient or practitioner;

(i) Governmental fraud or abuse agencies and State licensing or certification agencies recognized by HCFA may disclose information as necessary in a judicial, administrative or other formal legal proceeding resulting from an investigation conducted by the agency;

(j) State and local public health officials to carry out their responsibilities, as necessary, to protect against a substantial risk to the public health; or

(k) As necessary for the Office of the Inspector General to carry out its statutory responsibilities.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985]

## §476.108 Penalties for unauthorized disclosure.

A person who discloses information not authorized under Title XI Part B of the Act or the regulations of this part will, upon conviction, be fined no more than \$1,000, or be imprisoned for no more than six months, or both, and will pay the costs of prosecution.

## §476.109 Applicability of other statutes and regulations.

The provisions of 42 U.S.C. 290dd-3 and 290ee-3 governing confidentiality of alcohol and drug abuse patients' records, and the implementing regulations at 42 CFR part 2, are applicable to PRO information.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

### PRO ACCESS TO INFORMATION

## §476.111 PRO access to records and information of institutions and practitioners.

(a) A PRO is authorized to have access to and obtain records and information pertinent to the health care services furnished to Medicare patients, held by any institution or practitioner in the PRO area. The PRO may require the institution or practitioner to provide copies of such records or information to the PRO.

(b) A PRO may obtain non-Medicare patient records relating to review performed under a non-Medicare PRO con-

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tract if authorized by those patients in accordance with State law.

(c) In accordance with its quality review responsibilities under the Act, a PRO may have access to and obtain information from, the records of non-Medicare patients if authorized by the institution or practitioner.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

## §476.112 PRO access to records and information of intermediaries and carriers.

A PRO is authorized to have access to and require copies of Medicare records or information held by intermediaries or carriers if the PRO determines that the records or information are necessary to carry out PRO review responsibilities.

## §476.113 PRO access to information collected for PRO purposes.

(a) Institutions and other entities must disclose to the PRO information collected by them for PRO purposes.

(b) Information collected or generated by institutions or practitioners to carry out quality review studies must be disclosed to the PRO.

## §476.114 Limitation on data collection.

A PRO or any agent, organization, or institution acting on its behalf, that is collecting information under authority of this part, must collect only that information which is necessary to accomplish the purposes of Title XI Part B of the Act in accordance with 44 U.S.C. Chapter 35, Coordination of Federal Reporting Services Information Policy.

### PRO RESPONSIBILITIES

## §476.115 Requirements for maintaining confidentiality.

(a) *Responsibilities of PRO officers and employees.* The PRO must provide reasonable physical security measures to prevent unauthorized access to PRO information and to ensure the integrity of the information, including those measures needed to secure computer files. Each PRO must instruct its officers and employees and health care institution employees participating in PRO activities of their responsibility